THE STROKE REHABILITATION CENTER OF SOUTHEASTERN WISCONSIN

MARQUETTE UNIVERSITY

MEDICAL COLLEGE OF WISCONSIN

The Stroke Rehabilitation Center of Southeastern Wisconsin Translational & Clinical Seed Award Program

2018 Request for Applications for Seed Awards

Release date: July 25, 2017

The Stroke Rehabilitation Center of Southeastern Wisconsin (SRC) is a collaborative research initiative between The Medical College of Wisconsin and Marquette University and is supported by the Advancing a Healthier Wisconsin Research and Education Program (AHW REP).

For the 2018 cycle, the SRC is set to fund 2 awards up to $50,000 each. These awards are intended to stimulate inter-institutional and interdisciplinary translational and clinical research in stroke rehabilitation. These awards will promote best practice in rehabilitation research by supporting teams with significant levels of interaction and integration. Competitive applications will fit with the AHW Five Year plan.

KEY DATES

RFA for 2018 Seed cycle release date: July 25, 2017

Intent to apply due: September 25, 2017 5:00 p.m. CDT

Full Application Invitation Issued: October 15, 2017

Application due in MCW Grants & Contracts Office: December 10, 2017, 11:59 a.m. CDT

Application deadline: December 15, 2017, 5:00 p.m. CDT

Notification of award: February 1-15, 2017

Project start date: April 1, 2018

Project end date: March 31, 2019

OVERVIEW & PURPOSE

ABOUT THE STROKE REHABILITATION CENTER OF SOUTHEASTERN WISCONSIN

In 2015, Marquette University and the Medical College of Wisconsin formed the Stroke Rehabilitation Center (SRC) of Southeast Wisconsin to advance research, clinical services, education and community engagement in the rehabilitation of movement and other functional disorders in stroke survivors. The SRC research focuses on translational research with patient centered rehabilitation outcomes and is guided by a community academic advisory board to engage the community in the mission of the center.

This seed award program is designed to advocate, facilitate, and foster the continuum of research from bench to bedside, and from bedside to community practice. In a sense, translational research focuses on discovery and the application of scientific findings into a real-world setting. It is the goal of the SRC to promote novel, innovative, multi-disciplinary stroke rehabilitation research to improve functional outcomes among stroke survivors.

GOALS OF THIS FUNDING OPPORTUNITY

The fundamental goal of this RFA is to stimulate clinical and translational stroke rehabilitation research through meaningful collaboration and high quality team science. This award uses a multiple PI model to encourage inter-institutional and interdisciplinary collaboration between clinical and basic biomedical scientists, social scientists, ethicists, engineers, biostatisticians, informatics specialists, and all members of clinical health care delivery teams.

FUNDS WILL BE PROVIDED TO:

- Support new and promising clinical and translational projects in stroke rehabilitation research;
- Maximize scientific interactions of junior investigators with senior investigators;
- Stimulate collaborative research between translational and clinical investigators within similar research areas;
- Foster interdisciplinary and inter-institutional collaborations;

- Support research in novel technologies and/or novel approaches and their applications to clinical practice and community health;

- Support projects that will provide preliminary data for new extramural grant submissions.

DEFINITIONS & REQUIREMENTS

CLINICAL & TRANSLATIONAL RESEARCH

This seed award program funds clinical and translational research according to the NIH definitions described below:

CLINICAL RESEARCH

The NIH definition of clinical research has three parts:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies
3. Outcomes research and health services research [1]

TRANSLATIONAL RESEARCH

Applications will be reviewed and considered for funding based on NIH-identified translational areas:

> Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption

of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science. [2]

[1] Glossary of Terms for Human Subjects Protection and Inclusion Issues, based on the 1997 Report of the NIH Director's Panel on Clinical Research.
[2] National Institutes of Health. RFA-RM-07-007: Institutional Clinical and Translational Science Award (U54) Mar2007.

SPECIAL EMPHASIS CATEGORIES

Special emphasis categories for 2018 include neuroimaging, new rehabilitation technologies, and rehabilitation outcomes studies. Research in these areas is not a requirement for the award; however, additional review weight will be applied to these studies as being in alignment with a focus of the SRCI.

T-LEVELS

Applications must provide a T-level designation for the proposed research according to the translational continuum described below, based on NIH guidelines.

Proposals for T1-T2 studies will be grouped and reviewed together; likewise proposals for T3-T4 studies will be grouped and reviewed together.

- T-0 proposals that are only T-0 are *not* eligible to apply. T-0 research can be described as:
  - Pre-clinical approaches designed to inform an investigator about a pathway, pathophysiology, or treatment approach. Examples include:
    - animal models of human disease, human blood or cell lines
    - development of questionnaires, computational models, and human physiological studies
  - "Bench" research which may or may not require approvals from human or animal use committees.
- T-1 Translation to Humans
  - Studies with human participants that yield knowledge about human behavior, physiology, pathophysiology and the potential for intervention (i.e. diagnoses, therapies, etc.)
  - Findings from basic research are tested for clinical effect and/or applicability. [3]
- T-2 Translation to Patients
  - Test new interventions under controlled environments to form the basis for clinical application and evidence-based guidelines. [3]
  - Yield knowledge about the efficacy of the interventions in optimal settings. [3]

NOTE: Seed studies in T-3 and T-4 levels would provide preliminary evidence to

bolster competitiveness for larger studies in the following areas:

- T-3 Translation to Practice
  - study health services and community-based participatory research (dissemination, communication, implementation)
  - Explore ways of applying recommendations or guidelines in general practice.[3]
  - Yield knowledge about how interventions work in real-world settings.[3]
- T-4 Translation to Communities/Population Health
  - Study factors and interventions that influence the health of populations.[3]
  - Obtain results to benefit society & improve global health in areas such as improving disease prevention and reducing medical costs.
- T-5 Policy-level Research
  Proposals that incorporate T5 in addition to one of T1 through T4 are eligible to apply.

[3] Source: Harvard Catalyst

PRINCIPAL INVESTIGATOR & STUDY TEAM ROLES

Note that for the purposes of this award and in the language of this RFA, the roles of Principal Investigator (PI) and Co-Principal Investigator (Co-PI) are equivalent. These are distinct and have different requirements from the roles of Investigator or Co-Investigator (Co-I).

- PI REQUIREMENTS
  - All projects must have an MCW PI.
  - All PIs must have a minimum of 5% effort and be fully vested in the project in both spirit and practice, and contribute actively on the project. It is possible – and encouraged – for PIs to seek institutional/department cost-sharing to support all or a portion of this or other effort, thereby leaving more funds available for other research expenses. In these cases, cost-sharing commitment documentation from the institution and/or department is required.
  - All PIs must have full-time or full professional effort status. Adjunct and part-time faculty are not eligible to apply as a PI.
  - This award allows for, but does not mandate, a multiple PI model. In cases where a project has multiple PIs one must be from MCW. The other PI may come from another CTSI partner institution (UWM, MU, MSOE, CHW, BRI, VA, FMLH). According to MCW corporate policy, the MCW PI will be primarily responsible for ensuring compliance with the scientific, safety, and ethical

responsibilities of the grant award.
  - The MCW PI will have the additional expectation of managing the award through the MCW *eBridge* system and through her/his department.
  - The MCW PI will be responsible for all grant reporting and fiscal management, and will be the main contact for budget and reporting management.
  - PIs are responsible for fulfilling reporting requirements as a condition of receipt and continuation of funds. Non-compliance of final and/or annual reporting could result in the rescinding of funds by SRC.
  - All PIs must be SRC Members. To become a member, please contact Moriah Iverson, Program Manager at miverson@mcw.edu.

- OTHER PERSONNEL
  - All personnel must be identified prior to the start date to replace any "to be named" positions proposed in the application.
  - Untenured junior faculty members and early-stage investigators are encouraged to apply.

- INTER-INSTITUTIONAL REQUIREMENT
  - Projects must be inter-institutional: the research team must include investigators from at least two of the five CTSI academic/research partner institutions (UWM, MU, MCW, MSOE, BCW) participating on a project.
  - Independent investigators from our clinical partners (VA, Froedtert, and CHW) may meet the requirement only if they are not primarily employed by MCW. An example of this would be a CHW nurse researcher who is primarily employed at CHW.
  - Community partners or investigators from other academic institutions would be welcomed additions to projects as Co-PIs or Co-Is, but alone do not meet the inter-institutional requirement. Please note, only primary employment will be used in determining institutional affiliation.
  - Faculty from the MU/MCW joint department of biomedical engineering should use their employment platform to determine institutional affiliation. However, two faculty alone from this department will not fulfill the inter-institutional requirement.

- All Investigators must be SRC Members by the time of the award. To become a member, please contact SRC Program Manager, Moriah Iverson at (414) 805-7341 or miverson@mcw.edu.
- Investigators that are interested in forming new collaborative relationships are encouraged to contact the SRC Seed Award Program Manager, Moriah Iverson at 414-805-7341 or miverson@mcw.edu.

REGULATORY REQUIREMENTS

Investigators must provide proof that all regulatory applications (IRB/IACUC, etc.) are in pre-submission or approved by time of application. If applicable, proof of any exempt status must be provided.

- If your project involves human subject research, all study team members must obtain CITI training.
- If your project involves FDA regulated research or NIH-funded clinical trials, all study team members must obtain training in Good Clinical Practice (GCP).
- Clinical trials that utilize any Froedtert Hospital (FH) resources – medical records, staff, facilities, equipment, etc. – in one way or another, must be reviewed via the Office of Clinical Research and Innovative Care Compliance (OCRICC) to ensure that FH has the staff, equipment, and other resources to successfully support the trial. Visit the OCRICC website for a list of services that require OCRICC approval.
  - Submitting your project's OCRICC application at the same time as the IRB submission will facilitate the FH administrative approval, and will typically follow notification of MCW/FH IRB approval within an average of 3 business days.
- Applicants are encouraged to contact CTSI IRB Navigator, Sonia Maldonado-Schmidt: smaldonado@mcw.edu and the MCW IRB office at MCWIRBReliance@mcw.edu at the time of application for assistance in managing IRB(s).
- This program has an accelerated nature and only a 12 month funding period. If your project requires working with federal agencies such as NIDA, FDA (e.g., IND, IDE

applications) or pharmacological agreements (e.g., clinical trial agreements, material transfer agreements), you must contact the SRC Seed Award Program Manager Moriah Iverson at miverson@mcw.edu or 414-805-7341 prior to applying.

BUDGET REQUIREMENTS

- Projects will be funded at a level of up to $50,000
- Project duration will be 12 months
- Funding under this RFA cannot be used as "bridge funding" for lapsed grants from any extramural source and is intended to be used for new projects.
- AHW REP funds cannot be used to supplant funds or resources that are available from other sources. However, matching funding and opportunities to leverage AHW funds to obtain other sources of financial support are encouraged.
- No "indirect costs" may be charged. For more information on allowable expenses, please view the Advancing a Healthier Wisconsin Research and Education Program Award Administration Manual (PDF).
- Faculty salaries are subject to the NIH salary cap (FY15 Executive Level II salary cap of $181,500).

PROCEDURE

HOW TO APPLY

FIRST STEP: THE ONLINE INTENT TO APPLY FORM MUST BE COMPLETED AND SUBMITTED BY September 15, 2017 5:00 P.M. CDT.

REQUIRED APPLICATION MATERIALS

Once the Intent to Apply Form is reviewed and approved, applicants will be sent a link to an online application form which must be submitted along with the following documents:

1. 2018 SRC Seed Award Proposal Form (available October 15, 2017)
2. Budget and Budget Justification Form (1 each per partnering institution/agency) NOTE: If cost-sharing, please indicate this within your application on the budget justification and/or within a Letter of Support; cost-sharing commitment forms are

no longer required at the time of application and need only be provided from MCW departments during the Just-in-Time period prior to receipt of award.

3. NIH Biographical Sketch is required for all PIs; Co-PIs; Investigators; Co-Investigators (limit 5 pages per individual)
4. AHW Goals Alignment Form
5. AHW Non-Supplanting Attestation Form is required for each PI; Co-PI;
6. Investigator; Co- Investigator
7. Letter of Support for project from the Department Chair(s) for each PI; Co-PI (if required by your institution)
8. Letters of Support from each Co-Investigator to the PI(s)

A link to the above forms will be sent with the LOI approval notice.

All applications must be routed through eBridge and must be received by the MCW Grants & Contracts Office (GCO) no later than 5 business days before the submission deadline in this RFA. Different departments may have different deadlines for obtaining departmental approvals prior to receipt by the GCO.

EBRIDGE FUNDING PROPOSAL SMARTFORM GUIDANCE

- General Proposal Information
  - Question 3.0 Type of Program – select "Research"
  - Question 5.0 Sponsor – select "AHW-Research and Education Program"
  - Question 6.0 Type of Organization – select "Internal"
  - Question 6.2, Internal Organization – select "AHW-Research and Education Program"
- Proposal Attachments
  - Question 2.1 Sponsor Application – upload your completed SRC Seed proposal form and any additional required documents. Please create a single PDF file of the full application to upload.

ADDITIONAL REQUIREMENTS BY INSTITUTION

For MU investigators, the application must be registered via the routine Proposal Registration process with the Office of Research and Sponsored Programs prior to submission. This process is required for proposals in which MU is the prime applicant and those for which MU is the collaborating applicant receiving funds. Remember that Marquette requires that a signed institutional letter of intent is in hand from all sub-awardees or collaborating institutions who

will be receiving funds (i.e. MCW, UWM, MSOE, etc.) from a grant in which MU is the prime applicant prior to submission. Please contact an ORSP staff member early in your application preparation process as we can assist with forms, budget formulation, proofreading, securing sub-award letters of intent, etc.

For UWM investigators, full applications must be routed using the WISPER system and approved by the Office of Sponsored Programs prior to submission to MCW. UWM applicants with new collaborators must process the sub-award within the MCW timeline. Letters of intent do not require a WISPER record.

For MSOE investigators, please contact Sheku Kamara, Dean of Applied Research, 277- 7416, kamara@msoe.edu

REVIEW CRITERIA

To ensure that the results of scientific research will be used to directly benefit human health, proposals in all disciplines relevant to stroke rehabilitation will be considered for funding. Criteria that must be met for funding of any proposal include:

- Clear potential to directly translate anticipated results into improved stroke rehabilitation outcomes for our southeast Wisconsin community; and
- Potential for proposed studies, when completed, to generate extramural funding.

Upon approval of the Intent to Apply you will be emailed a personalized link to proceed to a full application. The SRC Review Committee will initially review all applications for technical feasibility and compliance with above requirements. SRC Review Committee is comprised of members from partner institutions Marquette University (MU), Medical College of Wisconsin (MCW), Milwaukee School of Engineering (MSOE), and University of Wisconsin-Milwaukee (UWM). External reviewers may be included in the review process. All applications will undergo peer-review, an in-person panel review, and a post-panel review.

Maintaining confidentiality throughout the peer review process is essential to allow for the candid exchange of scientific opinions and evaluations; and to protect trade secrets, commercial or financial information, and information that is privileged or confidential. Similar to the NIH peer review process, the SRC is committed to protect the integrity of and to maintain confidentiality in peer review. See Guide Notice NOT-OD-14-073 and NOT-OD-15-106.

Projects will be reviewed based on their selected Translational T-level according to specific review criteria for each T-level grouping: T-1 and T2 will be grouped and reviewed together and T-3 and T-4 will be grouped and reviewed together.

FUNDING ACKNOWLEDGMENT:

Important Reminder – Please acknowledge the AHW REP when publishing papers, patents, projects, and presentations resulting from the use of SRC resources. Please see page 21 of *AHW REP Award Administration Manual (PDF)* for the Acknowledgement Policy.

RESOURCES FOR APPLICANTS

Please contact the SRC Program Manager, Moriah Iverson at (414) 805-7341 or miverson@mcw.edu with any questions.